REMARKS

In view of the foregoing amendments and the following representations, reconsideration and allowance of the above-identified application is respectfully requested.

Claims 1-12 and 14-23 are in the present application.

In the Office Action dated April 3, 2007, the Examiner rejected claims 1-23 under 35 U.S.C. § 102(e) as being anticipated by Phillips, United States Patent No. 6,645,988.

In response to this rejection Applicants have amended claim 1 to specifically indicate that the multi-layered dosage forms comprises a coating around the proton pump inhibitor (PPI) and that the multi-layered dosage form is free of sodium bicarbonate. Claim 1 has also been amended to indicate that the coating around the proton pump inhibitor is a film-forming polymeric material or a congealable solid material. No new matter has been added by this amendment. Support for this amendment can be found in claim 13 as originally filed and on page 5, lines 8-10 of the specification.

Claim 13 has been canceled without prejudice because the limitation of claim 13 has been incorporated into claim 1. Claims 14-17 have been amended to correct their dependency from cancelled claim 13 to amended claim 1.

Claim 18 has also been amended to clarify that the recited PPI granules are coated with the film-forming polymeric material or congealable solid material. Support for this amendment can be found on page 10, lines 6-32 of the specification and the Examples which appear on pages 14-28 of the specification.

Applicants respectfully submit that the amended claims are patentable over the Phillips reference because the pending claims describe a multi-layered dosage form that is not disclosed or suggested by the Phillips reference. As discussed on pages 2 and 3 of the present specification, it was Applicants' goal to develop a dosage from that was free of both enteric polymers and sodium bicarbonate. Applicants wanted to eliminate enteric polymers because they can lead to delayed and variable absorption patterns for the same dosage forms based upon pH variability of the gastro-intestinal tract. Applicants also wanted to eliminate sodium bicarbonate because it generates unwanted gas in the stomach with the potential for detrimental side effects in patients with gastro-esophageal disease. The multi-layered dosage form recited in the pending claims successfully obtained these goals.

The Phillips reference describes a number of PPI and antacid formulations and many potential excipients that can be used in the proposed formulations. Most of the formulations in the Phillips reference are designed for use in oral solutions or suspensions. All the multi-layered dosage formulations in the Phillips reference require sodium bicarbonate and/or enteric coated PPI or fail to disclose or suggest the coating of the PPI with a film forming polymer or congealable material. For example, the dosage forms described in Example II on Col. 25 lines 5-30 comprise 20 mg of omeprazole uniformly dispersed in 975 mg of sodium bicarbonate. Also disclosed in Example II is a 975 mg sodium bicarbonate tablet with a bore hole containing PRILOSEC (an enteric coated omeprazole product) pellets.

Applicants have reviewed the full disclosure of the Phillips reference and located

the following suggestions of multi-layered tablets but none of these disclosures suggest the multi-layered composition with a coated PPI as recited in the pending claims:

Col. 25, lines 5-30 (discussed above and employs sodium bicarbonate);

Col. 25, lines 31-43 (employs sodium bicarbonate);

Col. 50, lines 3-16 (employs sodium bicarbonate);

Col. 51, line 55 to Col. 52, line 2 (a very general disclosure of buffers and particle size with no mention of coating the PPI);

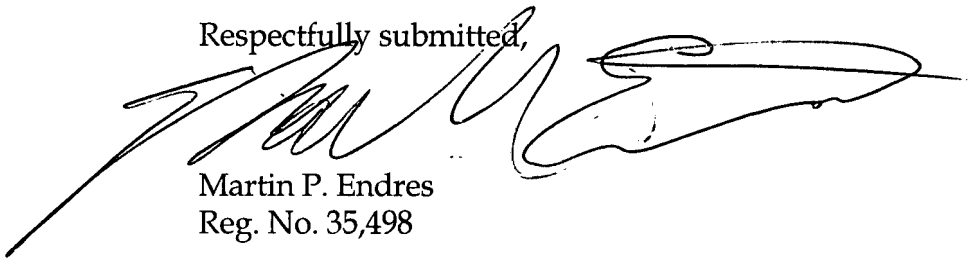
Col. 69, line 56 to Col. 75, line 17 (employs sodium bicarbonate and/or enteric material).

The Phillips reference also contains discussions of multi-component systems (NOT multi-layered dosage forms) for example: Col. 18, line 10 to Col. 25, line 3 discloses a number of fast dissolving suspension tablets and Col. 59, line 7 to Col. 69, line 55 disclose a number of multi-component systems for forming stable PPI suspensions or solution.

It is respectfully submitted that the Phillips reference does not anticipate the present claims because there is no teaching or suggestion in the Phillips reference to prepare a sodium bicarbonate free and enteric free multi-layer dosage form wherein the PPI is coated with a film-forming polymeric material or congealable solid material.

Based upon the foregoing amendments and representations, Applicants respectfully submit that the rejection of the claims in the above-identified application have been overcome and should be withdrawn. Early and favorable action is earnestly solicited.

Respectfully submitted,



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